No. 83-1925

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

HILLSBOROUGH COUNTY, FLORIDA, *et al.*,
Appellants,

v.

AUTOMATED MEDICAL LABORATORIES, INC.

On Appeal from the United States Court of Appeals for the Eleventh Circuit

BRIEF FOR GROCERY MANUFACTURERS OF AMERICA, INC. AS AMICUS CURIAE IN SUPPORT OF APPELLEE

PETER BARTON HUTT
Counsel of Record
Covington & Burling
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20044
(202) 662-5522

STEPHEN A. BROWN
Grocery Manufacturers of America, Inc.
Suite 800
1010 Wisconsin Avenue, N.W.
Washington, D.C. 20007
(202) 337-9400

Counsel for Amicus Curiae

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TABLE OF AUTHORITIES

CASES: Page

Armour & Co. v. *North Dakota*, 240 U.S. 510 (1916) . 11
Blank v. *United States*, 400 F.2d 302 (5th Cir. 1968) .. 14
Brown v. *Maryland*, 12 Wheat. (25 U.S.) 419 (1827) .. 12
Corn Products Refining Co. v. *Eddy*, 249 U.S. 427 (1919) 12
Hebe Co. v. *Shaw*, 248 U.S. 297 (1919) 11
Louisiana v. *Mathews*, 427 F. Supp. 174 (E.D. La. 1977) 15
McDermott v. *Wisconsin*, 228 U.S. 115 (1913) 12
Price v. *Illinois*, 238 U.S. 446 (1915) 11
Savage v. *Jones*, 225 U.S. 501 (1912) 12
United States v. *Calise*, 217 F. Supp. 705 (S.D.N.Y. 1962) 16
United States v. *Great Atlantic & Pacific Tea Co.*, 92 F.2d 610 (1937) 12
United States v. *Shinnick*, 219 F. Supp. 789 (E.D.N.Y. 1963) 15
United States v. *Steinschreiber*, 219 F. Supp. 373 (S.D.N.Y. 1963), *aff'd per curiam*, 326 F.2d 759 (2d Cir.), *cert. denied*, 376 U.S. 962 (1964) 14
Weigle v. *Curtice Bros. Co.*, 248 U.S. 285 (1919) 11

CONSTITUTION AND STATUTES:

United States Constitution, Commerce Clause .. 4, 5, 6, 12
21 U.S.C. § 301 *et seq.* 2, 13
21 U.S.C. § 331(k) 14
42 U.S.C. § 262 ..... 2, 14
42 U.S.C. § 264(a) 2
2 Stat. 806 (1813) 9
3 Stat. 677 (1822) 9
9 Stat. 237 (1848) 8
22 Stat. 451 (1883) 8
24 Stat. 209 (1886) 9
25 Stat. 549 (1888) 8
26 Stat. 414 (1890) 8
26 Stat. 1089 (1891) 8

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29 Stat. 604 (1897) 8
30 Stat. 151 (1897) 8
30 Stat. 246 (1898) 8
30 Stat. 947 (1899) 8
32 Stat. 728 (1902) 2, 10
34 Stat. 768 (1906) 10, 11, 12
52 Stat. 1040 (1938) 2, 13
58 Stat. 682 (1944) 2, 14, 15
62 Stat. 582 (1948) 14
76 Stat. 780 (1962) 2, 14
78 Stat. 269 (1964) 24
84 Stat. 1297 (1970) 2, 14
86 Stat. 559 (1972) 2, 14
"An Act against selling unwholesome Provisions," 31 Food Drug Cosm. L.J. 246 (1976) 7
The General Laws and Liberties of the Massachusetts Colony (1672 ed.) 7

LEGISLATIVE MATERIALS:

15 Cong. Rec. 2427 (March 31, 1884) 9
H.R. 5916, 45th Cong., 3d Sess. (1879) 9
H.R. Rep. No. 1880, 49th Cong., 1st Sess. (1886) 9
H.R. Rep. No. 2118, 59th Cong., 1st Sess. (1906) 11
H.R. Rep. No. 91-1035, 91st Cong., 2d Sess. (1970) ... 14
S. Rep. No. 361, 74th Cong., 1st Sess. (1935) 13

REGULATIONS:

21 C.F.R. § 5.10(a)(iv) 16
21 C.F.R. § 5.10(a)(v) 16
21 C.F.R. § 10.30 28
21 C.F.R. § 10.40 28

Table of Authorities Continued

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FEDERAL REGISTER NOTICES:

37 Fed. Reg. 12865 (June 29, 1972) 16

49 Fed. Reg. 49838 (December 24, 1984) 29

FDA blood regulation notices 17-19

National Blood Policy of 1973:

39 Fed. Reg. 9326 (March 9, 1974);

39 Fed. Reg. 32702 (September 10, 1974) ... 3, 16, 17, 26

MISCELLANEOUS:

F. Accum, *A Treatise on Adulterations of Food and Culinary Poisons* (1820) 7

"AFDO Takes First Step To Selective Preemption," Food Chemical News, June 25, 1984, at 49-53 23

4 AFDOUS Quart. Bull. 3 (1940) 23

5 AFDOUS Quart. Bull. 2 (1941) 22

5 AFDOUS Quart. Bull. 8 (1941) 23

31 AFDOUS Quart. Bull. (Proceedings Issue) 73 (1967) 23

33 AFDOUS Quart. Bull. (Proceedings Issue) 46 (1969) 23

37 AFDOUS Quart. Bull. (Proceedings Issue) 19 (1973) 23

"An Inquiry into Conflicting and Duplicative Regulatory Requirements Affecting Selected Industries and Sectors," 96th Cong., 2nd Sess. (1980) (Joint Committee Print) 25

L.C. Beck, *Adulterations of Various Substances Used in Medicine and the Arts* (1846) 7

W.D. Bigelow, *Foods and Food Control*, USDA Bull. No. 69, pts. I-IV (1902) 8

W.D. Bigelow, *The Development of Pure Food Legislation*, 7 Science 505 (April 15, 1898) 9

G.M. Burditt, *The Importance of Uniformity Among State Food and Drug Laws*, 26 Food Drug Cosm. L.J. 96 (1971) 26

Table of Authorities Continued

Page

"Consumer Protection Activities of State Governments," H.R. Rep. No. 445, 88th Cong., 1st Sess. (1963) 23, 24

"Consumer Protection Activities of State Governments," H.R. Rep. No. 921, 88th Cong., 1st Sess. (1963) . 24

T.F. De Voe, *The Market Assistant* (1867) 8

T.F. De Voe, *The Market Book: A History of the Public Markets of the City of New York* (1862) 7

F.E. Fisher, *Federal/State Concurrent Regulations*, 29 Food Drug Cosm. L.J. 20 (1974) 24

Food From Farmer to Consumer: Report of the National Commission on Food Marketing (1966) 25

Food Law Institute, *Federal Food, Drug, and Cosmetic Law Administrative Reports, 1907-1949* (1951) .. 20, 21

R.L. Frank, *Food Labelling—The Case for National Uniformity*, 34 Food Drug Cosm. L.J. 512 (1979) 26

W.W. Goodrich, *The Applicability of the Federal Food, Drug, and Cosmetic Act to Intrastate Commerce*, 3 Food Drug Cosm. L.J. 332 (1948) 14

C.B. Gray, *Regulation and Federalism*, 1 Yale J. Reg. 93 (1983) 28

K. Helrich, *The Great Collaboration: The First One Hundred Years of the Association of Analytical Chemists* (1984) 22

J.P. Hile, *Remarks on Eliminating Duplication and Promoting Uniformity*, 44 AFDO Quart. Bull. 37 (1980) 21

W. Janssen, *America's First Food and Drug Laws*, 30 Food Drug Cosm. L.J. 665 (1975) 7

R.A. Kondratas, *Death Helped Write the Biologics Law*, 16 FDA Consumer 23 (1982) 10

J.F. Lakey, *Uniform State Food Laws and Amendments*, 14 Food Drug Cosm. L.J. 179 (1959) 24

Table of Authorities Continued

Page

H.M. Meyer, *Does Government Regulation Work?*, in D.B. Johnson ed., *Blood Policy Issues and Alternatives* 91 (1976) 17

C.R. Miller, *Uniform Food Laws*, 6 Food Drug Cosm. L.J. 924 (1951) 26

Office of Technology Assessment, *Blood Policy & Technology*, Rep. No. OTA-H-260 (1985) 26

J.C. Pearson, *Uniform State Food Laws*, 14 Food Drug Cosm. L.J. 183 (1959) 21

H.A. Prentice, *Uniform Food Laws*, 4 Food Drug Cosm. L.J. 502 (1949) 26

Public Administration Service, *A Study of State and Local Food and Drug Programs* (1965) 24

E.L. Randall, *Factors Affecting the States' Adoption of the Food-Additives Law as Well as Other Recent Amendments to the Federal Food, Drug, and Cosmetic Act*, 14 Food Drug Cosm. L.J. 172 (1959) .. 24

W.F. Reindollar, *The Association of Food and Drug Officials*, 6 Food Drug Cosm. L.J. 52 (1951) 22

Report of the White House Conference on Food, Nutrition and Health (1969) 25

O. Salthe, *State Food, Drug and Cosmetic Legislation and its Administration* 6 L. & Contemp. Prob. 165 (1939) 13

R.P. Schipa, *The Desirability of Uniform Food Law*, 3 Food Drug Cosm. L.J. 518 (1948) 26

L. Shattuck, *Report of the Sanitary Commission of Massachusetts* (1850) 7

E.R. Squibb, *Proposed Legislation on the Adulteration of Food and Medicine* (1879) 9

T.E. Sullivan, *The Desirability of Uniformity Between State and Federal Laws on Food Additives*, 16 Food Drug Cosm. L.J. 34 (1961) 24

Table of Authorities Continued

Page

T.E. Sullivan, *The Effect of Uniform Legislation on State Control*, 3 Food Drug Cosm. L.J. 444 (1948) 23

T.E. Sullivan, *Uniform State Laws and the Impact of Federal Amendments*, 14 Food Drug Cosm. L.J. 167 (1959) 24

M.S. Thompson, *What Price Uniformity?*, 30 Food Drug Cosm. L.J. 567 (1975) 26

J. Trichter, *The Federal Food Drug and Cosmetic Act and the New York Sanitary Code*, 11 Food Drug Cosm. L.J. 86 (1956) 23-24

W.G. Tucker, *Food Adulteration: Its Nature and Extent, and How to Deal with It* (1903) 10

USDA, *Barriers to International Trade in Farm Products* (1939) 24

USDA, *Officials Charged with the Enforcement of Food Laws in the United States and Canada*, Bu. of Chem. Circ. No. 16 (1904) and Bu. of Chem. Circ. No. 16 (rev. 1905) 8

A.J. Wedderburn, *Special Report on the Extent and Character of Food Adulterations*, USDA Bull. No. 32 (1892) 8

O.J. Wiemann, *Report on the Revision of the Uniform State Food, Drug and Cosmetic Bill*, 17 Food Drug Cosm. L.J. 218 (1962) 23

H.W. Wiley, *Drugs and Their Adulterations and The Laws Relating Thereto*, 2 Washington Medical Annals 205 (1903) 9

Uniform State Food, Drug and Cosmetic Bill, Food Drug Cosm. L. Rep. (CCH) ¶ 10,102 23

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BRIEF FOR GROCERY MANUFACTURERS OF AMERICA, INC. AS AMICUS CURIAE IN SUPPORT OF APPELLEE

INTEREST OF AMICUS CURIAE

The Grocery Manufacturers of America, Inc., is a trade association representing companies that manufacture food and other grocery products for nationwide distribution. Its members include the principal grocery manufacturers in this country. Members of the association ship products in interstate commerce for sale throughout the country and are subjected

both to federal regulatory requirements and to numerous different or additional regulatory requirements imposed by various state, county, and local governments. The association and its members therefore have a major interest in assuring that regulatory requirements imposed on all food and drugs, including blood and blood products, are uniform across the country in order to facilitate nationwide production and marketing without restrictive trade barriers. The association and its members strongly support concurrent jurisdiction of state, county, and local governments to enforce uniform national standards identical with federal requirements, but oppose additional or different requirements on a local level that impede commerce for no public health benefit.[1]

SUMMARY OF ARGUMENT

Congress has authorized comprehensive federal regulation of all aspects of blood and blood products — from donation of blood, through processing and storage, to ultimate use — under three separate statutes: (1) the Biologics Act of 1902[2], which was recodified as part of the Public Health Service Act of 1944[3] and subsequently amended to confirm the inclusion of blood products[4], (2) the Federal Food, Drug, and Cosmetic Act of 1938[5], as subsequently amended by the Drug Amendments of 1962[6] and the Drug Listing Act of 1972[7] to provide additional regulatory authority, and (3) the communicable disease prevention provisions in section 361(a) of the Public Health Service Act.[8] No aspect of the collection, processing, marketing, and

[1]All parties have consented to the filing of this brief by letters that have been filed with the Clerk of the Court in accordance with Rule 36.

[2]32 Stat. 728 (1902).

[3]58 Stat. 682, 702 (1944), 42 U.S.C. § 262.

[4]84 Stat. 1297, 1308 (1970).

[5]52 Stat. 1040 (1938), 21 U.S.C. § 301 *et seq.*

[6]76 Stat. 780 (1962).

[7]86 Stat. 559 (1972).

[8]58 Stat. 682, 703 (1944), 42 U.S.C. § 264(a).

use of blood remains unregulated under these pervasive federal statutory authorities.

Blood is a relatively recent article of commerce. As more has become known about it through the advancement of the biological sciences, federal regulation has become increasingly more detailed and stringent. Federal regulatory efforts culminated in the development in 1973 of a National Blood Policy, which explicitly stated that it is "the policy of the United States Government:"

> "(7) To employ the full regulatory authorities now invested in the Federal Government and to seek such additional authority as may be necessary and appropriate for the purpose of assuring uniform adherence to the highest attainable standards of practice in blood banking, including plasmapheresis and plasma fractionation."[9]

Pursuant to this National Blood Policy, the Food and Drug Administration (FDA) has used the statutory authority cited above to promulgate an extraordinary number of implementing regulations governing all aspects of blood banking, including plasmapheresis and plasma fractionation. As a result of these federal regulatory efforts, there is no conceivable gap in public protection relating to blood and blood products, and no public health justification for different or additional state, county, or local requirements that are not identical to the federal requirements.

In defiance of the National Blood Policy and the comprehensive and detailed federal regulations implementing it, Hillsborough County has imposed its own additional and different regulatory requirements. Instead of enforcing requirements identical to those under federal law, Hillsborough County has chosen to enforce different requirements. If Hillsborough County can constitutionally enforce different and additional requirements, not identical to the federal requirements, then

[9]39 Fed. Reg. 9326, 9329-9330 (March 8, 1974); 39 Fed. Reg. 32702, 32703 (September 10, 1974).

every state, county, and local government in the United States has equal constitutional power to do so. Such a result would frustrate the purpose of the National Blood Policy and implementing federal regulations and would represent the very balkanization of commerce in blood and blood products sought to be prevented by the Commerce Clause of the Constitution.

The problem raised by this case is illustrative of the general lack of national uniformity in the regulation of all food and drugs in the United States. Today there is one nationwide market for food and drugs. Recognizing this fact, Congress has enacted a remarkable array of regulatory statutes, and FDA has implemented them with comprehensive and detailed regulations, to govern every aspect of these products from production to use. But just as this case reveals in the specific example of blood and blood products, contrary to the congressional intent of a unified national regulatory system there are different and additional laws and regulations for food and drugs on the state, county, and local levels of government, for no public health reason.

This problem has historical origins. In the early days of this country, food and drugs were consumed where they were grown.[10] As cities began to develop, local food markets were established to fill the need. Town ordinances were adopted to regulate the food supply sold in those markets. As cities grew larger, and food and drug distribution expanded, county laws were established to regulate them as well. By the mid-1800s, states were also enacting regulatory laws in this area. Because the production and distribution of food and drugs were still primarily local or regional matters throughout the 1800s, however, there was no federal law establishing a nationwide regulatory policy for these articles of commerce until after 1900.

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[10]Even through the end of the 19th century, most drug products were natural botanicals and the same herbs and other natural products were often used for both food and drug purposes.

Shortly after 1900, Congress enacted the first nationwide food and drug laws. Because of this Court's narrow interpretation of the Commerce Clause at that time, however, these statutes were very limited in their jurisdiction. Food and drugs were not covered if they were produced and distributed locally. Nor were they covered after their shipment in interstate commerce. It is not surprising, therefore, that Supreme Court decisions during the early 1900s ruled that these federal laws did not preclude different requirements in state and local laws.

These early federal laws were subsequently replaced by more modern laws that now pervasively regulate every aspect of food and drugs. These federal laws, and the detailed regulations promulgated by FDA to implement them, reflect a clear federal intent to occupy this field. By the time these modern laws were enacted, however, it was too late for them to serve as a model for state and local legislation or to make enactment of state and local legislation unnecessary in this area. Different and additional state and local laws regulating food and drugs were already well-established and have continued to this day.

Beginning with the development of a significant nationwide commerce in food and drugs, and the resulting efforts to enact federal legislation to assure consumer protection with respect to these products, concurrent attempts were made to achieve uniformity between the federal requirements and the state and local requirements, through informal means of persuading state and local governments to adopt laws and regulations uniform with the federal laws and regulations. The Association of Analytical Chemists, the Association of Food and Drug Officials, various governmental agencies and organizations, and others have continuously encouraged the principle of national uniformity for at least the past 100 years, but without success. Notwithstanding the intent of Congress to enact a comprehensive national regulatory scheme, the country is no closer to national uniformity in the regulation of food and drugs today than it was in the late 1800s. The efforts at achieving uniformity through informal persuasion have repeatedly failed and will continue to fail in the future.

The net result is that the country continues to suffer from nonuniform state and local laws and regulations governing the production and marketing of food and drugs, including blood and blood products. There is no incentive for state and local governments to adopt a uniform national regulatory policy, and no statutory penalty if they fail to do so. The only effective limit on state and local action is the Commerce Clause of the Constitution. It is thus imperative that this Court establish general principles under the Commerce Clause that will preclude continuation of the present patchwork of laws and regulations throughout the country, and instead require national uniformity in the best interests of the country.

The federal government has a preeminent interest in assuring uniformity of food and drug regulation. To accomplish that purpose, Congress and FDA have established a pervasive system of federal regulation of food and drugs that leaves no room for supplementation by state and local governments. A crucial role remains for state and local regulatory authorities in the enforcement of uniform requirements established under the leadership of the federal government.

ARGUMENT

I. Laws Regulating Food and Drugs Were Initially Enacted by State and Local Governments Before the United States Became One National Market-Place, But Have Been Superseded by Comprehensive Modern Federal Statutes and Regulations.

A. The Growth of State and Local Laws in the 1800s

Colonial America was an agrarian economy. People consumed the food and herbal drugs they produced. Even those who lived in small towns kept livestock and their own gardens.

As urban centers began to develop, local food markets were established to serve them. In his classic study, De Voe traced the history of the public markets of the City of New York from

the origin of the West India Company's store in the 1630s through the 1840s.[11] As these markets were established, the City of New York adopted various regulatory requirements to control them. These requirements largely reflected the English common and statutory law.

Although many of these early laws were directed to specific commodities or problems[12], a number were directed more generally at preventing any form of adulteration.[13] As cities grew larger, concern about public health expanded. Beginning in 1820, a series of publications in England and the United States documented adulteration of the food and drug supply, and its consequences to both the public pocketbook and the public health.[14] Lemuel Shattuck's landmark report on public health in 1850 documented the decrease in average life expectancy at birth in America's large urban centers and identified the adulteration of food and drugs as a matter of public health concern.[15] Shattuck recommended the establishment of local boards of health which would "endeavor to prevent the sale and use of unwholesome, spurious, and adulterated articles, dangerous to the public health, designed for food, drink, or medicine."[16]

Five years after his earlier book, De Voe published another study in which he noted the great expansion in public trade and

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[11] T.F. De Voe, *The Market Book: A History of the Public Markets of the City of New York* (1862).

[12] *E.g.*, *The General Laws and Liberties of the Massachusetts Colony* 17 (beef and pork), 53 (fish), and 54 (fish) (1672 ed.). *See generally*, W. Janssen, *America's First Food and Drug Laws*, 30 Food Drug Cosm. L.J. 665 (1975).

[13] In 1785, Massachusetts enacted "An Act against selling unwholesome Provisions," which is reproduced in 31 Food Drug Cosm. L.J. 246 (1976).

[14] *E.g.*, F. Accum, *A Treatise on Adulterations of Food and Culinary Poisons* (1820); L.C. Beck, *Adulterations of Various Substances Used in Medicine and the Arts* (1846).

[15] L. Shattuck, *Report of the Sanitary Commission of Massachusetts* (1850).

[16] *Id.* at 220.

the need for increased regulation to protect both the producer and the consumer:

> "The producer is often hundreds of miles in one direction, while the consumer may be as many hundred in another, from the *mart* at which the productions were sold and purchased. * * *
>
> A great trade has imperceptively grown upon us (particularly in New York), which I have sometimes thought, would have been more profitable to both producer and consumer, if proper laws, and practical, honest heads, had been placed over these vast interests, which so much affect the general health and comfort, as well as the *pockets* of our over-taxed citizens. . ."[17]

Following Shattuck's report and this expansion in trade, boards of health were established in cities, counties and states throughout the country.[18] Congress itself initially enacted broad food and drug legislation for the District of Columbia in 1888[19] and substantially strengthened it in 1898.[20]

B. Enactment of Federal Laws in the 1900s

Although statutes were enacted by Congress to regulate foreign commerce in food and drugs during the 1800s,[21] no

[17]T.F. De Voe, *The Market Assistant* 9 (1867).

[18]There is no compilation of all of these laws and regulations. Some of the state laws were collected and described or reproduced in A.J. Wedderburn, *Special Report on the Extent and Character of Food Adulterations*, USDA Bull. No. 32 (1892) and W.D. Bigelow, *Foods and Food Control*, USDA Bull. No. 69, pts. I-IV (1902). State regulations, and county and local laws and regulations, were not included. *See also* USDA, *Officials Charged with the Enforcement of Food Laws in the United States and Canada*, Bu. of Chem. Circ. No. 16 (1904) and Bu. of Chem. Circ. No. 16 (rev.)(1905).

[19]25 Stat. 549 (1888).

[20]30 Stat. 246 (1898).

[21]*E.g.*, 9 Stat. 237 (1848)(imported drugs); 22 Stat. 451 (1883) and 29 Stat. 604 (1897)(imported tea); 26 Stat. 414 (1890), 26 Stat. 1089 (1891), 30 Stat. 151, 210 (1897), and 30 Stat. 947, 951 (1899)(imported and exported food).

federal law was enacted during the 19th century to deal broadly with the safety and effectiveness of food and drugs marketed throughout the United States.[22]

In January 1879, Dr. E.R. Squibb delivered a major address to the Medical Society of the State of New York, proposing enactment of a nationwide food and drug law.[23] He began his remarks with a strong statement on the need for uniform national regulation of these articles:

> "It is self-evident that a law to be most effective in preventing the adulteration of food and medicine should be general or national in order to secure universality and uniformity of action . . ."[24]

Only ten days later, the first comprehensive federal legislation was introduced in Congress.[25] Because of strong feelings in Congress that this was properly a matter for state and local regulation[26], federal legislation was debated in Congress from 1879 to 1906. Throughout this time, the need for national uniformity in regulation of food and drugs was an important argument in favor of the legislation.[27] The Director of the

[22]A statute to regulate smallpox vaccine enacted in 2 Stat. 806 (1813) was repealed in 3 Stat. 677 (1822) after an error in its administration, on the ground that the subject matter should be left to regulation by the states.

[23]E.R. Squibb, *Proposed Legislation on the Adulteration of Food and Medicine* (1879).

[24]*Id.* at 3.

[25]H.R. 5916, 45th Cong., 3d Sess. (1879).

[26]As a result of congressional concern about the constitutionality of laws to control oleomargarine, 15 Cong. Rec. 2427(March 31, 1884), H.R. Rep. No. 1880, 49th Cong., 1st Sess. (1886),that legislation was enacted under the guise of a complex system of taxation, 24 Stat. 209 (1886).

[27]For example, the Chief of the USDA Food Laboratory argued for national legislation because "By no other means can we hope to secure laws uniform in their scope, requirements and penalties among ourselves . . ." W.D. Bigelow, *The Development of Pure Food Legislation*, 7 Science 505, 512 (April 15, 1898). The Chief of the USDA Bureau of Chemistry stated that legislation was necessary "to secure uniformity in the composition of drugs . . ." H.W. Wiley, *Drugs and Their Adulterations and The Laws Relating Thereto*, 2 Washington Medical Annals 205 (1903).

Bureau of Chemistry of the New York State Department of Health noted the need for uniform national regulation of food and drugs in 1903:

> ". . . it is very certain that the widely differing statutes relating to our food supply in the different States have worked much mischief, been the cause of much confusion, and seriously embarassed some useful industries. I think all who have studied the matter will be inclined to admit that uniformity in our food laws is much to be desired . . ."[28]

As has often happened in the history of food and drug regulation, a tragedy intervened to spur the enactment of national legislation. The Biologics Act of 1902[29] was enacted as a result of the distribution in St. Louis of tetanus-infected diphtheria antitoxin that resulted in the death of several children.[30] The law required that biological drugs sold in interstate commerce must be licensed and must be produced in licensed establishments.

Four years later, Congress enacted the Food and Drugs Act of 1906[31], which prohibited the adulteration or misbranding of any food or drug. Consistent with the concern expressed throughout the development of the legislation, the House Report stated that:

> ". . . the laws and regulations of the different States are diverse, confusing, and often contradictory. What one State now requires the adjoining State may forbid. Our food products are not raised principally in the States of their consumption.

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[28]W.G. Tucker, *Food Adulteration: Its Nature and Extent, and How to Deal with It* 21 (1903).

[29]32 Stat. 728 (1902).

[30]R.A. Kondratas, *Death Helped Write the Biologics Law*, 16 FDA Consumer 23 (1982).

[31]34 Stat. 768 (1906).

> State boundary lines are unknown in our commerce, except by reason of local regulation and laws, such as State pure-food laws. It is desirable, as far as possible, that the commerce between the states be unhindered. One of the hoped-for good results of a national law on the subject of pure foods is the bringing about of a uniformity of laws and regulations on the part of the States within their own several borders."[32]

The 1906 Act, however, did not establish the basis for a comprehensive national regulatory scheme. It applied only to unbroken packages in interstate commerce, and only to the actual label of the product. Although premarket approval was required for biological drugs under the 1902 Act, no such authority was granted for other drugs under the 1906 Act. Nor was power granted to require informative labeling for either food or drugs. Thus, there were major regulatory gaps in the 1906 Act, with the result that these matters were left to the states.

These gaps were recognized in the decisions rendered by this Court under the 1906 Act, upholding state regulations which imposed requirements different from or in addition to those imposed by the federal government. The Court upheld a number of state requirements that applied only to food held for retail sale, and not contained in original unbroken packages after it had been shipped in interstate commerce.[33] These decisions were based on the jurisdictional provisions of the 1906 Act, which reached only goods that remained "unloaded, unsold, or in original unbroken packages" after interstate shipment[34], and on the restrictive construction of the Commerce

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[32]H.R. Rep. No. 2118, 59th Cong., 1st Sess. 5-6 (1906).

[33]*Hebe Co.* v. *Shaw*, 248 U.S. 297 (1919); *Weigle* v. *Curtice Bros. Co.*, 248 U.S. 285 (1919); *Armour & Co.* v. *North Dakota*, 240 U.S. 510 (1916); *Price* v. *Illinois*, 238 U.S. 446 (1915).

[34]34 Stat. 768, 771, § 10 (1906).

Clause power from which those provisions were derived.[35] That narrow jurisdictional limitation was later eliminated in the 1938 Act.

Two of this Court's decisions under the 1906 Act were also based on the limited scope and coverage of the substantive provisions of that Act.[36] In both cases, the state requirements related to mandatory labeling, a matter not covered by the 1906 Act. Because the Court concluded that the federal regulatory scheme did not "cover the entire ground"[37] and that Congress had "limited the scope of its prohibitions,"[38] the state requirements were upheld.

In only one case arising under the 1906 Act did this Court confront a state regulation that affected an aspect of food labeling that was affirmatively regulated by that Act.[39] Both federal and state law required the food in question (a blend of corn and cane syrup) to bear an identity statement. The federal law did not specify the words to be used in such a statement. The state, however, imposed a specific form of words to be used and prohibited all others.[40] The Court's decision cannot be explained as an example of irreconcilable conflict between state and federal law, since the labeling requirement imposed by state law was also permitted under the federal statute. This Court stated that:

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[35]*See Brown* v. *Maryland*, 12 Wheat. (25 U.S.) 419 (1827) and *United States* v. *Great Atlantic & Pacific Tea Co.*, 92 F.2d 610 (1937).

[36]*Corn Products Refining Co.* v. *Eddy*, 249 U.S. 427 (1919); *Savage* v. *Jones*, 225 U.S. 501 (1912).

[37]249 U.S. at 434, 225 U.S. at 532.

[38]225 U.S. at 532.

[39]*McDermott* v. *Wisconsin*, 228 U.S. 115 (1913).

[40]Section 8 of the Food and Drugs Act of 1906 provided that "mixtures" or "compounds" would not be deemed misbranded if sold under "distinctive names." 34 Stat. 768, 770, § 8 (1906). The state statute applied to "mixtures" of certain syrups, but prescribed specific names under which they were to be sold. 228 U.S. at 125-126.

> "Conceding to the state the authority to make regulations consistent with the Federal law for the further protection of its citizens against impure and misbranded food and drugs, we think to permit such regulation as is embodied in the statute is to permit a State to discredit and burden legitimate Federal regulations of interstate commerce, to destroy rights arising out of the Federal statute which have accrued both to the Government and the shipper, and to impair the effect of a Federal law which has been enacted under the Constitutional power of Congress over the subject."[41]

Thus, the state regulation was invalidated.

The limitations relating to both jurisdiction and substantive authority under the 1906 Act were removed by Congress in the Federal Food, Drug, and Cosmetic Act of 1938.[42] Under that statute, FDA is empowered to regulate all labeling, to impose any requirements for product information, to regulate every aspect of interstate commerce, to exercise premarket approval over new drugs and food additives, and to cover every other matter relating to the safety and effectiveness of food and drugs. When Congress considered enactment of this law, it stated that, recognizing the "problem of uniformity," the "States have unanimously urged the Federal Government to take leadership in modernizing existing law."[43] The technical adviser to the principal Senate sponsor and floor manager of the legislation reported a year after the 1938 act became law that all states had comprehensive food and drug laws at that time.[44] He recommended state legislation uniform with the new federal legislation:

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[41]228 U.S. at 133-134.

[42]52 Stat. 1040 (1938), 21 U.S.C. § 301 *et seq.*

[43]S. Rep. No. 361, 74th Cong., 1st Sess. 3 (1935).

[44]O. Salthe, *State Food, Drug and Cosmetic Legislation and its Administration*, 6 L. & Contemp. Prob. 165, 167 (1939).

> "When the state legislatures delegate power to state officials to promulgate regulations there should be some definite provisions for uniformity of action with the federal laws, so as to eliminate the confusion that would result in trying to comply with conflicting control."[45]

Congress has also amended the law since 1938 to provide still further authority for FDA. In 1948, Congress expanded the jurisdiction of the 1938 Act to include any action with respect to a food or drug that results in the article becoming adulterated or misbranded after shipment in interstate commerce.[46] The Drug Amendments of 1962[47] increased FDA authority over all drugs and the Drug Listing Act of 1972[48] provided FDA with authority to determine vital information about all drug products marketed in this country.

In 1944, Congress recodified the entire Public Health Service Act.[49] Two provisions in that law provide FDA with regulatory authority over drugs. Section 351 of the Public Health Service Act[50] recodified the provisions of the Biologics Act of 1902. As noted above, these provisions require premarket approval of biological drugs and include full power over the production and labeling of these products. In 1970, as a result of conflicts between court decisions[51], Congress amended section 351 to make it clear that it covered blood, blood components, and blood derivatives.[52]

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[45] *Id.* at 174-175.

[46] 62 Stat. 582 (1948), amending 21 U.S.C. § 331(k). *See* W.W. Goodrich, *The Applicability of the Federal Food, Drug, and Cosmetic Act to Intrastate Commerce*, 3 Food Drug Cosm. L.J. 332 (1948).

[47] 76 Stat. 780 (1962).

[48] 86 Stat. 559 (1972).

[49] 58 Stat. 682 (1944).

[50] *Id.* at 702, 42 U.S.C. § 262.

[51] *Compare United States* v. *Steinschreiber*, 219 F. Supp. 373 (S.D.N.Y. 1963), *aff'd per curiam*, 326 F.2d 759 (2d Cir.), *cert. denied*, 376 U.S. 962 (1964), *with Blank* v. *United States*, 400 F.2d 302 (5th Cir. 1968).

[52] 84 Stat. 1297, 1308 (1970). *See* H.R. Rep. No. 91-1035, 91st Cong., 2d Sess. 1-2 (1970).

The second important provision in the Public Health Service Act is section 361[53], which broadly authorizes any action necessary "to prevent the introduction, transmission, or spread of communicable diseases" in intrastate or interstate commerce. This provision allows FDA to undertake whatever form of regulation of food or drugs may be necessary to protect the public from any source of communicable disease.[54]

II. Comprehensive Modern Statutes and Regulations Assure Every Citizen that Food and Drugs Are Safe and Effective Throughout Every Jurisdiction in this Country.

The federal statutes enacted, amended, and strengthened throughout the 1900s now provide FDA with comprehensive authority to regulate every aspect of the food and drug supply. The nature of the subject matter, the consistent declaration of congressional purpose in enacting these statutes, the pervasive coverage of intrastate and interstate commerce, the comprehensive authority over every aspect of food and drugs, the dominant federal interest in a nationwide regulatory system for food and drugs, and the detailed implementing regulations promulgated by FDA, evince a congressional intent to occupy this field. Additional or different state and local laws and regulations obstruct and frustrate this congressional purpose and thus can no longer be justified.

A. The Collection, Processing, Marketing,and Use of Blood and Blood Products in this Country Are Thoroughly Regulated by FDA Pursuant to These Federal Statutes

Prior to 1972, the Biologics Act of 1902 and the later-enacted sections 351 and 361 of the Public Health Service Act were administered by the United States Public Health Service. In

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[53] 58 Stat. 682, 703 (1944), 42 U.S.C. § 264(a).

[54] *E.g.*, *Louisiana* v. *Mathews*, 427 F. Supp. 174 (E.D. La. 1977); *United States* v. *Shinnick*, 219 F. Supp. 789 (E.D.N.Y. 1963).

1972, however, the administration of these statutes was transferred to FDA.[55] In 1962, moreover, the status of blood as a "drug" under the Federal Food, Drug, and Cosmetic Act was upheld in the courts.[56] Thus, the consolidation in 1972 of all statutory authority for the regulation of blood and blood products in FDA set the stage for development of a single comprehensive federal regulatory approach.

At the same time that this regulatory authority was consolidated in FDA, the Department of Health, Education, and Welfare (HEW), within which FDA was located, undertook to establish a National Blood Policy. That National Blood Policy, adopted in 1973[57], brought together all interested private and public organizations to consider both regulatory and nonregulatory aspects of providing an adequate supply of vital blood products for the needs of the country. The National Blood Policy was designed:

> "(4) To encourage, foster, and support measures to enhance resource-sharing and area-wide cooperation in the collection, processing, distribution, and utilization of blood, in order to make the most effective use of the national supply."[58]

As part of the National Blood Policy, HEW determined that it was "the policy of the United States Government:"

> "(7) To employ the full regulatory authorities now vested in the Federal Government and to seek such additional authority as may be necessary and appropriate for the purpose of assuring uniform adherence to the highest

[55]37 Fed. Reg. 12865 (June 29, 1972), 21 C.F.R. § 5.10(a)(iv) & (v).

[56]*United States* v. *Calise*, 217 F. Supp. 705 (S.D.N.Y. 1962).

[57]39 Fed. Reg. 9326 (March 8, 1974); 39 Fed. Reg. 32702 (September 10, 1974).

[58]39 Fed. Reg. 9327, 9328 (March 8, 1974).

> attainable standards of practice in blood banking, including plasmapheresis and plasma fractionation."[59]

No additional authority was identified at that time, or in the ten years since then, that would be needed to achieve those "highest attainable standards." The implementation plan for the National Blood Policy stated that "the coordination of inventories across the nation that is called for in the following plan will make better use of periodic surpluses and will help to even out blood supplies to minimize the effects of localized shortages and to reduce the absolute numbers of donors who must be recruited during a given period."[60] It was intended to "organize blood banks and the transfusion facilities they serve within a national system"[61] organized and coordinated by the American Blood Commission.

Under its consolidated statutory authority, and in conformity with the National Blood Policy, FDA began in 1972 to apply new regulatory requirements to blood and blood products (shortened to "blood" in the following discussion).[62] FDA required registration of blood establishments[63], promulgated regulations governing current good manufacturing practices (GMP) in the collection, processing, and storage of blood[64], determined that advertising for blood is subject to section

[59]39 Fed. Reg. 9326, 9329 (March 8, 1974); 39 Fed. Reg. 32702 (September 10, 1974).

[60]39 Fed. Reg. at 9328.

[61]*Id.*

[62]*See generally*, H.M. Meyer, *Does Government Regulation Work?*, in D.B. Johnson, ed., *Blood Policy Issues and Alternatives* 91, 93-99 (1976).

[63]37 Fed. Reg. 17419 (August 26, 1972); 38 Fed. Reg. 2965 (January 31, 1973); 40 Fed. Reg. 52788 (November 12, 1975). *See also* 45 Fed. Reg. 19316 (March 25, 1980); 45 Fed. Reg. 64601 (September 30, 1980); 49 Fed. Reg. 34448 (August 31, 1984).

[64]39 Fed. Reg. 18614 (May 28, 1974); 40 Fed. Reg. 53532 (November 18, 1975). Additional recordkeeping requirements were proposed, 41 Fed. Reg. 18095 (April 30, 1976), but withdrawn as unnecessary, 43 Fed. Reg. 59098 (December 19, 1978).

502(n) of the 1938 Act and the implementing regulations[65], established responsibility for regulation of containers for collection or processing of blood[66], promulgated donor classification labeling requirements[67], began to regulate specific product labeling[68], announced proposed requirements for records and reports of adverse reactions and product experiences[69], proposed to require reports on errors and accidents in plasmapheresis[70], conducted a donor safety workshop for leukapheresis[71], established guidelines for various procedures[72], revised the calibration requirements for certain blood equipment[73], proposed revised labeling requirements for blood[74], revised hepatitis testing restrictions[75], conducted a review of all the federal blood regulations[76], subjected therapeutic plasma exchange to FDA regulation[77], and took a wide variety of

[65]39 Fed. Reg. 43654 (December 17, 1974).

[66]40 Fed. Reg. 33971 (August 13, 1975).

[67]40 Fed. Reg. 53040 (November 14, 1975); 41 Fed. Reg. 4955 (February 3, 1976); 41 Fed. Reg. 8523 (February 27, 1976); 42 Fed. Reg. 11018 (February 25, 1977); 43 Fed. Reg. 2142 (January 13, 1978).

[68]43 Fed. Reg. 15779 (April 14, 1978).

[69]44 Fed. Reg. 24233 (April 24, 1979).

[70]45 Fed. Reg. 52821 (August 8, 1980).

[71]45 Fed. Reg. 58969 (September 5, 1980).

[72]45 Fed. Reg. 63144 (September 23, 1980); 42 Fed. Reg. 25381 (May 17, 1977); 46 Fed. Reg. 24694 (May 1, 1981); 46 Fed. Reg. 52430 (October 27, 1981); 46 Fed. Reg. 48768 (October 2, 1981); 46 Fed. Reg. 49204 (October 6, 1981); 49 Fed. Reg. 13079 (April 2, 1984).

[73]44 Fed. Reg. 34515 (June 15, 1979); 45 Fed. Reg. 9261 (February 12, 1980).

[74]45 Fed. Reg. 72416 (October 31, 1980); 46 Fed. Reg. 47623 (September 29, 1981).

[75]44 Fed. Reg. 76811 (December 28, 1979); 46 Fed. Reg. 35121 (July 7, 1981); 46 Fed. Reg. 36134 (July 14, 1981); 48 Fed. Reg. 46815 (October 14, 1983); 49 Fed. Reg. 26717 (June 29, 1984).

[76]47 Fed. Reg. 12358 (March 23, 1982).

[77]48 Fed. Reg. 14048 (April 1, 1983).

other actions. In addition, FDA continued to establish safety standards for all of the blood products allowed by FDA to be marketed pursuant to federal licenses: platelet concentrate (human)[78], normal serum albumin (human) and plasma protein fraction (human)[79], plasma collected and manufactured by plasmapheresis[80], blood grouping serum[81], single donor plasma (human)[82], reagent red blood cells[83], whole blood (human)[84], blood group substances[85], and antihemophilic factor (human)[86].

[78]36 Fed. Reg. 6835 (April 9, 1971); 39 Fed. Reg. 2008 (January 16, 1974); 40 Fed. Reg. 4300 (January 29, 1975); 42 Fed. Reg. 10982 (February 25, 1977); 45 Fed. Reg. 2852 (January 15, 1980); 45 Fed. Reg. 27926 (April 25, 1980); 45 Fed. Reg. 45924 (July 8, 1980); 47 Fed. Reg. 49017 (October 29, 1982).

[79]37 Fed. Reg. 12505 (June 24, 1972); 40 Fed. Reg. 7456 (February 20, 1975); 42 Fed. Reg. 27575 (May 31, 1977); 42 Fed. Reg. 44228 (September 2, 1977); 48 Fed. Reg. 19897 (May 3, 1983); 48 Fed. Reg. 34480 (July 29, 1983); 49 Fed. Reg. 1685 (January 13, 1984); 49 Fed. Reg. 2243 (January 19, 1984).

[80]37 Fed. Reg. 17419 (August 26, 1972); 38 Fed. Reg. 19362 (July 20, 1973); 39 Fed. Reg. 26161 (July 17, 1974); 39 Fed. Reg. 35187 (September 30, 1974); 40 Fed. Reg. 41799 (September 9, 1975); 41 Fed. Reg. 10762 (March 12, 1976); 42 Fed. Reg. 18129 (April 5, 1977); 42 Fed. Reg. 21772 (April 29, 1977); 42 Fed. Reg. 25381 (May 17, 1977); 42 Fed. Reg. 25339 (May 17, 1977); 42 Fed. Reg. 37545 (July 22, 1977); 43 Fed. Reg. 9804 (March 10, 1978); 43 Fed. Reg. 19461 (May 5, 1978); 44 Fed. Reg. 60332 (October 19, 1979); 45 Fed. Reg. 28358 (April 29, 1980); 45 Fed. Reg. 45924 (July 8, 1980); 45 Fed. Reg. 79092 (November 28, 1980); 45 Fed. Reg. 80500 (December 5, 1980); 46 Fed. Reg. 57480 (November 24, 1981); 47 Fed. Reg. 12358 (March 23, 1982); 47 Fed. Reg. 15329 (April 9, 1982); 47 Fed. Reg. 30968 (July 16, 1982).

[81]38 Fed. Reg. 31312 (November 13, 1973); 40 Fed. Reg. 52623 (November 11, 1975); 42 Fed. Reg. 54534 (October 7, 1977); 42 Fed. Reg. 61257 (December 2, 1977); 43 Fed. Reg. 19844 (May 9, 1978); 46 Fed. Reg. 35122 (July 7, 1981); 47 Fed. Reg. 22519 (May 25, 1982).

[82]40 Fed. Reg. 52619 (November 11, 1975); 42 Fed. Reg. 59873 (November 22, 1977).

[83]40 Fed. Reg. 52621 (November 11, 1975); 43 Fed. Reg. 10554 (March 14, 1978).

[84]43 Fed. Reg. 2890 (January 20, 1978); 43 Fed. Reg. 34457 (August 4, 1978); 45 Fed. Reg. 72422 (October 31, 1980); 48 Fed. Reg. 33494 (July 22, 1983).

[85]43 Fed. Reg. 11716 (March 21, 1978); 44 Fed. Reg. 20673 (April 6, 1979).

[86]45 Fed. Reg. 22975 (April 4, 1980).

FDA has, in short, considered every aspect of the regulation of blood and blood products. Without doubt, it has decided to issue regulatory requirements in some areas where state, county, and local governments might conclude not to regulate, and it has decided to refrain from issuing regulatory requirements in other areas where state, county, or local governments might conclude that regulation should be undertaken. If every state, county, or local government in the country were to decide — like Hillsborough County — to issue its own different or additional requirements on top of those imposed by FDA, there would be chaos. FDA's comprehensive and detailed regulatory scheme for blood exhibits an extraordinarily deep evaluation of all aspects of blood regulation, and permits no supplementary requirements by state, county, or local governments. Such additional or different requirements would clearly frustrate the federal purpose of a comprehensive National Blood Policy and uniform national regulatory requirements to implement it.

B. The Production, Processing, Marketing, and Use of All Food and Drugs in this Country Are Regulated by FDA in an Equally Comprehensive Way

This case illustrates only one aspect of FDA regulation, for blood and blood products. Other drugs and food are also subject to detailed and comprehensive regulatory control by FDA.

III. Repeated Attempts To Achieve National Uniformity in the Regulation of Food and Drugs by Informal Persuasion Have Failed.

Following enactment of the Food and Drugs Act of 1906, FDA's predecessor agency, the USDA Bureau of Chemistry, made major efforts to implement the congressional intent[87] of national uniformity in the regulation of food and drugs. The 1914 Annual Report of the Bureau of Chemistry[88] reported

[87]Note 32 *supra*.

[88]The annual reports of the Bureau of Chemistry and FDA are reprinted in Food Law Institute, *Federal Food, Drug, and Cosmetic Law Administrative Reports, 1907-1949* (1951).

cooperative efforts with state officials "for the purpose of fixing working standards for foods and drugs" that "should serve as a uniform guide in the enforcement of the food and drug laws throughout the country" and thus "should very largely overcome the lack of uniformity."[89] A report on the progress achieved by the Bureau of Chemistry during the first ten years under the 1906 Act, contained in the 1917 Annual Report, related attempts to deal with "much confusion and apparent conflict between the local and Federal laws and the local and Federal administration of the laws," resulting in "extra cost, which naturally was passed on to the ultimate consumer."[90] The 1921 Annual Report similarly reflected the fact that "both officials and manufacturers complained greatly of the lack of uniformity in the exercise of food control by the Federal and State Governments:"[91]

> "Lack of uniformity increases the cost of doing business, and the increased cost is usually passed on to the consumer. It arises not merely from differences in the various laws but also from differences in the interpretation of the laws by the officials and the application by them of different standards to the same product in different jurisdictions."

In 1924, an attempt was made to devise "a uniform method of procedure" for regulation of both federal and state food and drug laws.[92] FDA has continued to deal with this persistent problem of nonuniform food and drug laws in the years since.[93]

State and local officials have also been concerned about this problem. The original constitution of the Association of Official

[89]1914 Annual Report at 1, *id.* at 321.

[90]1917 Annual Report at 12-13, *id.* at 366-367.

[91]1921 Annual Report at 7, *id.* at 459.

[92]1924 Annual Report at 26, *id.* at 592.

[93]*E.g.*, J.C. Pearson, *Uniform State Food Laws*, 14 Food Drug Cosm. L.J. 183 (1959); J.P. Hile, *Remarks on Eliminating Duplication and Promoting Uniformity*, 44 AFDO Quart. Bull. 37 (1980).

Agricultural Chemists (now the Association of Official Analytical Chemists), adopted in 1884, stated that the objectives were "to secure, as far as possible, uniformity in legislation . . . and uniformity and accuracy in the methods and results" of analysis.[94] AOAC has consistently sought this objective for 100 years.

In 1897, representatives from ten states met "for the purpose of forming a national Association . . . with the end in view of producing, as nearly as conditions and laws would permit, uniformity of action in the enforcement of such [food and drug] laws."[95] The constitution of the resulting organization, adopted in 1897, stated that the purpose was:

> ". . . to promote and foster such legislation as would tend to protect public health and prevent deception . . . — also to promote uniformity in legislation and rulings . . . ."[96]

That organization, now the Association of Food and Drug Officials (AFDO), includes as members the regulatory officials from federal, state, county, and local governments. AFDO has urged the principle of national uniformity from its first organization. In 1941, for example, the AFDO President wrote an editorial criticizing "trade barriers that force many producers and manufacturers to live under the virtual dictatorship of localized bureaucracy," and urging state food and drug officials to "Discourage the enactment of laws that make it impossible for legitimate industry of one state to engage in trade in another under conditions which are fair and equitable" and to "Encourage the enactment of uniform laws and the adoption of uniform regulations looking toward honest protection of the consumer."[97] That year, AFDO adopted a resolution to express "active and continuing interest in the enactment of uniform

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[94]K. Helrich, *The Great Collaboration: The First One Hundred Years of the Association of Official Analytical Chemists* 9 (1984).

[95]W.F. Reindollar, *The Association of Food and Drug Officials*, 6 Food Drug Cosm. L.J. 52, 53 (1951).

[96]*Id.* at 54.

[97]5 AFDOUS Quart. Bull. 2 (1941).

legislation" and "emphatically express its disapproval of the tendency toward the enactment of legislation which constitutes definite barriers to Commerce between the states."[98] Since 1940, the Association has repeatedly adopted resolutions urging enactment of uniform food and drug legislation.[99] Nonetheless, in 1973 the Association found it necessary to pass yet another resolution acknowledging, as well as disapproving, "a growing trend . . . that some States and local agencies are passing laws, regulations, or ordinances which are inconsistent with the principle of uniformity to which A.F.D.O.U.S. is committed."[100] More recently, yet another AFDO committee has made recommendations for achieving national uniformity in food and drug regulation.[101]

AFDO has sponsored the development of uniform state legislation under both the 1906 Act and the 1938 Act, and has periodically revised this legislation to reflect changes in the federal law.[102] Since 1938, state officials have admonished their colleagues to achieve adoption of this legislation, and to administer state and local laws in a manner consistent with federal interpretations,[103] but to no avail.

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[98]5 AFDOUS Quart. Bull. 8 (1941).

[99]*E.g.*, 4 AFDOUS Quart. Bull. 3-4 (1940); 31 AFDOUS Quart. Bull. (Proceedings Issue) 73 (1967); 33 AFDOUS Quart. Bull. (Proceedings Issue) 46-47 (1969).

[100]37 AFDOUS Quart. Bull. (Proceedings Issue) 19 (1973).

[101]"AFDO Takes First Step To Selective Preemption," Food Chemical News, June 25, 1984, at 49-53.

[102]Note 44 *supra;* O.J. Wiemann, *Report on the Revision of the Uniform State Food, Drug and Cosmetic Bill*, 17 Food Drug Cosm. L.J. 218 (1962). The current version of the Uniform State Food, Drug and Cosmetic Bill may be found in Food Drug Cosm. L. Rep. (CCH) ¶ 10,102. Earlier versions under the 1938 Act may be found in "Consumer Protection Activities of State Governments," H.R. Rep. No. 445, 88th Cong., 1st Sess. 88, 104 (1963).

[103]For examples of statements of state and local food and drug officials endorsing national uniformity, see T.E. Sullivan, *The Effect of Uniform Legislation on State Control*, 3 Food Drug Cosm. L.J. 444 (1948); J. Trichter,

Dozens of reports and articles reflect the repeated failure of these attempts to achieve uniformity through informal persuasion. A USDA report in 1939 found that varying or inconsistent state requirements created increasingly serious barriers to national food distribution.[104] Two studies conducted by the House Committee on Government Operations in 1963 revealed widely differing approaches to regulation of food and drugs among the state governments.[105] A two-year study on state and local food and drug programs, conducted by the Public Administration Service for FDA, concluded in 1965 that:

> "The general food and drug laws of the states fail to reveal a basic uniformity among themselves or inadequate correspondence with federal legislation. * * * Differences in laws and regulations are excessive, and many serve no useful purpose; the total body of state and local food and drug laws is a confusing and disjointed mass."[106]

The National Commission on Food Marketing, established by Congress to appraise the marketing structure of the industry[107], stated in 1966 that "conflicts among the profusion of

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The Federal Food, Drug and Cosmetic Act and the New York Sanitary Code, 11 Food Drug Cosm. L.J. 86 (1956); T.E. Sullivan, *Uniform State Laws and the Impact of Federal Amendments*, 14 Food Drug Cosm. L.J. 167 (1959); E.L. Randall, *Factors Affecting the States' Adoption of the Food-Additives Law as Well as Other Recent Amendments to the Federal Food, Drug, and Cosmetic Act*, 14 Food Drug Cosm. L.J. 172 (1959); J.F. Lakey, *Uniform State Food Laws and Amendments*, 14 Food Drug Cosm. L.J. 179 (1959); T.E. Sullivan, *The Desirability of Uniformity Between State and Federal Laws on Food Additives*, 16 Food Drug Cosm. L.J. 34 (1961); F.E. Fisher, *Federal/State Concurrent Regulations*, 29 Food Drug Cosm. L.J. 20 (1974).

[104] USDA, *Barriers to Internal Trade in Farm Products* (1939).

[105] "Consumer Protection Activities of State Governments," H.R. Rep. No. 445, 88th Cong., 1st Sess. (1963), and H.R. Rep. No. 921, 88th Cong., 1st Sess. (1963).

[106] Public Administration Service, *A Study of State and Local Food and Drug Programs* 8 (1965).

[107] 78 Stat. 269 (1964).

State regulations . . . are a significant burden on interstate trade in food products" and concluded that:

> "We therefore believe that a concerted effort should be made to effect uniformity among State regulations that obstruct trade in foods across State lines."[108]

The Report of the White House Conference on Food, Nutrition and Health in 1969 similarly found that "Under present Federal, State and local law, different and often inconsistent regulatory requirements . . . prevail throughout the Nation," and that these requirements:

> ". . . result in artificial trade barriers that impede the orderly marketing of foods, hinder sound nutrition, raise the cost of new foods to consumers, and directly interfere with the public interest. * * * This situation cannot be justified on public health grounds, and reflects the lack of any attempt to establish and maintain a national policy on foods that reflects the interest of consumers."[109]

The Report of the White House Conference therefore recommended "Uniform application of all regulatory requirements throughout the Nation, enforceable by Federal, State, and local officials."[110] A 1980 study by the Joint Economic Committee of Congress also reflected the fact that "in the area of drug labeling, State and Federal statutes can differ."[111] The problem of non-uniform laws, regulations, and interpretations has pro-

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[108] *Food From Farmer to Consumer: Report of the National Commission on Food Marketing* 112 (1966).

[109] *Report of the White House Conference on Food, Nutrition and Health* 124-125 (1969).

[110] *Id.* at 117.

[111] "An Inquiry into Conflicting and Duplicative Regulatory Requirements Affecting Selected Industries and Sectors," 96th Cong., 2d Sess. 24 (1980) (Joint Committee Print).

duced more articles in the Food Drug Cosmetic Law Journal, since its first issue in 1946, than any other subject.[112]

Thus, in defiance of the congressional intent to achieve a consistent and unified national regulatory program, it is apparent that none of the extensive attempts at persuasion during the past 100 years has brought the country nearer to national uniformity in the regulation of food and drugs. Such approaches have repeatedly failed and will continue to fail in the future.

IV. State and Local Laws and Regulations That Are Different From or in Addition To Federal Laws and Regulations Constitute Trade Barriers That Frustrate the Purpose of Comprehensive Federal Regulation in this Field.

The United States has become one large nationwide market for food and drugs. Although blood and blood products are comparatively recent articles of national commerce, compared to other drugs and to food, the market for blood and blood products has now become national and even international in scope.[113] It was this realization, indeed, that led to the development of the National Blood Policy in 1973.[114] The need for blood and blood products, like the need for other drugs and for food, knows no political boundaries. The National Blood Policy was formulated in 1973 precisely to allow the sharing of blood supplies within regions of the country or, in times of short

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[112] *E.g.*, notes 93 & 103 *supra;* R.P. Schipa, *The Desirability of Uniform Food Law*, 3 Food Drug Cosm. L.J. 518 (1948); H.A. Prentice, *Uniform Food Laws*, 4 Food Drug Cosm. L.J. 502 (1949); C.R. Miller, *Uniform Food Laws*, 6 Food Drug Cosm. L.J. 924 (1951); G.M. Burditt, *The Importance of Uniformity Among State Food and Drug Laws*, 26 Food Drug Cosm. L.J. 96 (1971); M.S. Thompson, *What Price Uniformity?*, 30 Food Drug Cosm. L.J. 567 (1975); R.L. Frank, *Food Labelling — The Case for National Uniformity*, 34 Food Drug Cosm. L.J. 512 (1979).

[113] Notes 58 & 60 *supra;* Office of Technology Assessment, *Blood Policy & Technology*, Rep. No. OTA-H-260, ch. 1 (1985).

[114] Note 57 *supra*.

supply, between regions.[115] Federal regulatory efforts were designed to achieve uniformity in regulation to facilitate that policy. Allowing state, county, and local governments to superimpose on the federal regulatory system additional or different requirements would frustrate the National Blood Policy and prevent the efficient distribution and use of these life saving products.

Nonuniform laws, regulations, interpretations and other requirements have a direct and immediate adverse impact upon the national interest. They result in an enormous economic burden upon consumers, with no corresponding public health benefits. A single uniform regulatory system, consistent with the pervasive regulatory program enacted by Congress and implemented by FDA, is more efficient and more effective than balkanized regulation through differing or additional requirements that vary from judisdiction to jurisdiction throughout the country.

Citizens who live in one part of the country are no less entitled to protection than those who live in another. Our citizens also travel widely throughout the country, and are entitled to the same protection in every state, county, and city they visit. Determinations about the safety of food and drugs must therefore be consistent in every jurisdiction in this country.

Recognition that Congress and FDA have established uniform requirements for the safety and effectiveness of food and drugs throughout the country will enhance consumer protection. Enforcement of such requirements will be accomplished more efficiently as state, county, and local officials join in a cooperative venture with federal officials to ensure nationwide compliance with clear and uniform regulatory requirements, thus substantially increasing the effectiveness of public expenditures.

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[115] *Id.*

National uniformity in food and drug regulation does not mean that state and local officials must be subservient to the federal government or that they cannot contribute to the development and consideration of improvements in the regulatory approach adopted by FDA. Under existing FDA regulations, state and local officials may petition FDA to change any existing regulation or interpretation, or to impose new requirements, in order to improve national regulatory policy.[116] State and local officials may similarly comment on all FDA proposals and otherwise participate in FDA proceedings.[117] Thus, a fully coordinated and consistent national regulatory policy, with the active participation of state and local officials, has been provided for under existing law.

In an article published in 1983, the Counsel to the Vice President stated that President Reagan's "New Federalism" initiative, which is designed to encourage greater responsibility at the state and local level, includes:

> ". . . recognition that state and local administration of regulatory programs may conflict in some instances with other goals of regulatory relief or with other important federal interests. For example, individual states may operate specific programs more effectively than the federal government, but the combined effect of disparate state regulatory standards may intolerably burden interstate commerce, thus requiring uniform federal regulation."[118]

Recognizing "the need for a strong central government to promote commerce and other federal interests,"[119] he distinguished between those matters that are primarily local in nature and those that involve such "burdens on interstate commerce"[120] that national uniformity is required.

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[116]21 C.F.R. § 10.30.

[117]21 C.F.R. § 10.40.

[118]C.B. Gray, *Regulation and Federalism*, 1 Yale J. Reg. 93 (1983).

[119]*Id.* at 95-96.

[120]*Id.* at 96.

As recently as December 1984, the Administrative Conference of the United States issued a report and recommendation that echoed these principles.[121] While recognizing that "state governments are normally in a better position than the federal government to determine the types of regulations that will serve the interests of the states' citizens," the report also found that "States sometimes have an incentive, however, to impose regulations that advance state interests at the expense of other states' interests or of national interests." The report concluded that, because of the limited "checks on state regulation that harms the national interest:"

> "states possess, in practice, the power to make regulatory choices that produce net benefits within the state but that produce substantial net detriments on a national level. Without an additional federal constraint on state regulatory power, states can be expected to regulate in this manner frequently."

The Administrative Conference therefore recommended that the problem of national uniformity in regulatory policies be directly pursued in order to protect nationwide interests.

State and local governments have clearly failed to recognize the comprehensive federal regulatory scheme for food and drugs that has been enacted into law by Congress and implemented by FDA during the past 50 years. This Court must therefore give effect to the congressional intent to establish one nationwide uniform regulatory system that will fully protect both the interests of consumers and the free flow of food and drugs in interstate commerce.

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[121]49 Fed. Reg. 49838 (December 24, 1984).

CONCLUSION

For the reasons set forth above, the judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

PETER BARTON HUTT
Counsel of Record
Covington & Burling
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20044
(202) 662-5522

STEPHEN A. BROWN
Grocery Manufacturers of
America, Inc.
Suite 800
1010 Wisconsin Avenue, N.W.
Washington, D.C. 20007
(202) 337-9400

Counsel for Amicus Curiae

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